UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 34

Serial Number: 07/985742
Filing Date: 4 December 1992
Appellant(s): Comai et al

MAILED
2-23-95

Schwedler
For Appellant

EXAMINER'S ANSWER

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1803.

This is in response to appellant's brief on appeal filed 25 November 1994.

(1) Status of claims.

The statement of the status of claims contained in the brief is correct.

(2) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The amendment (Paper No. 33) filed after the final rejection has been entered. The effect of entry is to moot issues 1 and 2 and modify issue 3 by removing some alternative references which are no longer prior art.

(3) Summary of invention.

The summary of invention contained in the brief is correct.

(4) Issues.

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

I. Issue 1 is moot.

II. Issue 2 is moot.

III. Whether claims 20, 22-28, 30, 33-36 and 43 were properly rejected under 35 USC 103 as obvious over Shah et al and Sanders et al taken with Richens et al.

IV. No change.

(5) Grouping of claims.

The rejection of claims 20, 22-27 and 33-35 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and no separate argument is found. See 37 C.F.R. 1.192(c)(5).

The rejection of claims 20, 22-27 and 33-36 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and no separate argument is found. See 37 C.F.R. 1.192(c)(5).

Each rejection of claims 20, 22-28, 30, 33-36 and 43 stands or falls together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and no separate argument is found. See 37 C.F.R. 1.192(c)(5).

(6) Claims appealed.

The copy of the appealed claims contained in the Appendix to the brief is correct.

(7) Prior Art of record.

US 4,940,835 Shah et al		10 July 1990 (filed 7 July 1986)
Sanders et al	Nucleic Acids Research Volume 15, pages 1543-1558	1987
Richens et al	Nucleic Acids Research Volume 15, pages 8451-8466	1987
Shepherd et al	Phytopathology Volume 77, pages 1668-1673	1987

(8) New prior art.

No new prior art has been applied in this examiner's answer.

(9) Grounds of rejection.

The following ground(s) of rejection are applicable to the appealed claims.

The rejection of claims 20, 22-27, and 33-35 under 35 U.S.C. 102(a) as being clearly anticipated by either Gowda et al or Wu et al is withdrawn in view of the after final amendment (Paper No. 33) and the Comai 131 Declaration of 16 November 1993.

The rejection of claims 20, 22-27, and 33-36 under 35 U.S.C. 102(a) as being clearly anticipated by Goldberg et al is also withdrawn in view of the after final amendment (Paper No. 33) and the Comai 131 Declaration of 16 November 1993.

Claims 20, 22-28, 30, 33-36, and 43 on appeal are rejected under 35 U.S.C. 103 as being unpatentable over Shah et al and Sanders et al taken with Richins et al [Gowda et al or Wu et al or Goldberg et al are removed as prior art by the after final amendment and the Comai 131 Declaration of 16 November 1993].

Shah et al disclosed foreign genes expressed under the control of the CaMV 35S promoter (a strong viral promoter) and the vectors, plant cells and plants containing same as well as a method of transforming dicot plants for operable expression of same. The CaMV 35S promoter used by Shah et al was disclosed by Sangers et al. Even though Shah et al taught use of strong promoters from other plant viral sources (e.g., '835, page 3, lines 25-30), specific viral sources were not listed. Thus the primary references differed from the claimed invention only in that a CaMV 35S promoter rather than an FMV 35S promoter was used.

The FMV 35S promoter was old at the time this invention was made in that Richins et al had already pointed out the location and identity of the FMV 34S promoter. This secondary reference described FMV and its relationship to CaMV and specifically identified the presently claimed promoter region which was said to be analogous both in structure and function to the CaMV 35S promoter (see Richins et al at Figure 2, Table I, paragraph spanning pages 8459-8460, Figure 5 and the second paragraph at page 8464, for example). Thus at the time this invention was made, it was obvious to one of ordinary skill in the art that FMV was a well-characterized, widely recognized source of strong

viral promoters and that the claimed FMV 35S promoter analogous to its counterpart in CaMV had already been identified.

It was also obvious to one of ordinary skill in the art at the time this invention was made to modify the primary references with the teachings of the secondary reference in order to obtain expression of foreign genes with yet another known plant viral promoter as suggested by Shah et al with a reasonable expectation of success and motivation to do so with the FMV 34S promoter in light of the teaching by Richins et al that the FMV 34S promoter was expected to be a strong promoter like its counterpart CaMV 35S promoter. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

Claims 20, 22-28, 30, 33-36 and 43 on appeal are rejected under 35 U.S.C. 103 as being unpatentable over Shah et al and Sanders et al taken with Richins et al and Shepherd et al.

Shah et al disclosed foreign genes expressed under the control of the CaMV 35S promoter (a strong viral promoter) and the vectors, plant cells and plants containing same as well as a method of transforming dicot plants for operable expression of same. The CaMV 35S promoter used by Shah et al was disclosed by Sangers et al. Even though Shah et al taught use of strong promoters from other plant viral sources (e.g., '835, page 3, lines 25-30), specific viral sources were not listed. Thus the primary references differed from the claimed invention only in that a CaMV 35S promoter rather than an FMV 35S promoter was used.

The FMV 35S promoter was old at the time this invention was made in that Richins et al had already pointed out the location and identity of the FMV 34S promoter. Richins et al described FMV and its relationship to CaMV and specifically identified the presently claimed promoter region which was said to be analogous both in structure and function to the CaMV 35S promoter (see Richins et al at Figure 2, Table I, paragraph spanning pages 8459-8460, Figure 5 and the second paragraph at page 8464, for example) and, thus, expected to be a strong promoter like its counterpart CaMV 35S promoter. This was echoed by Shepherd et al which taught that FMV was as amenable to cloning manipulation as CaMV (page 1668). Shepherd et al described the broad host range and high titer achievable with FMV in plant host cells and also compared CaMV and FMV promoters (page 1672). Thus at the time this invention was made, it was obvious to one of ordinary skill in the art that FMV was a well-characterized, widely recognized source of strong viral promoters and that the claimed FMV 35S promoter analogous to its counterpart in CaMV had already been identified.

It was also obvious to one of ordinary skill in the art at the time this invention was made to modify the primary references with the teachings of the secondary references in order to obtain expression of foreign genes with yet another strong plant viral promoter as suggested by Shah et al with a reasonable expectation of success and motivation to do so with the FMV 34S promoter in view of the teaching by Richins et al that the FMV 34S promoter was expected to be a strong promoter like its counterpart CaMV 35S promoter. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

(10) New ground of rejection.

This Examiner's Answer does not contain any new ground of rejection.

(11) Response to argument.

Issue I.

Arguments (pages 4-6, Brief) are moot as the rejection is withdrawn in light of the after final amendment and the Comai Declaration under 37 CFR 1.131 swearing behind the references.

Issue II.

Arguments (pages 6-7, Brief) are moot as the rejection is withdrawn in light of the after final amendment and the Comai Declaration under 37 CFR 1.131 swearing behind the references.

Issue III. Whether claims 20, 22-28, 30, 33-36 and 43 were properly rejected under 35 USC 103 as obvious over Shah et al and Sanders et al taken with Richens et al.

Appellant correctly notes (Brief, page 7) that alternative secondary references are removed as prior art by the after final amendment and the Comai Declaration under 37 CFR 1.131 swearing behind the references.

Appellant insists that the claimed FMV 34S promoter was not disclosed by Richins et al. This argument is not persuasive because Richins et al had already pointed out the location and identity of the claimed FMV 35S promoter and taught that the promoter was analogous both in structure and function to the CaMV 35S promoter. For example, Richins et al lined up the TATA boxes of CaMV 35S (Figure 5, top line) and FMV 34S strain DxS (Figure 5, middle line) in exactly the same manner as Appellant has done in this application (cf. Figure 5 of Richins et al with Figure 1 in the specification, TATA region alignment top line is CaMV 35S and the bottom line is FMV 34S strain DxS). In discussing Figure 5, Richins et al said at page 8460 that this promoter region was reported to be essential for high level expression of eucaryotic genes including those of plants. Indeed, Sanders et al among others had already demonstrated the strength of the CaMV 35S promoter region which had been widely used for expressing genes in plants.

The "subjective choice of sequence which best corresponded with the TATA box of CaMV" (page 8464, Richins et al) resulted in a teaching that sequences found at position 6893 were comparable to CaMV 35S (see Figure 5 which aligned the two regions). This is the region claimed by Appellant and to which Richins et al further called attention as being "essential for high level expression of eucaryotic genes including those of plants" (page 8460, Richins et al). Thus, attention was directed away from any

other TATA-like sequence. Downstream homologies which evidenced further close similarity between FMV and CaMV were not presented as promoters; there was no suggestion that promoter activity analogous to CaMV 35S was located anywhere else. Thus Appellants belief that discussions of other components of the FMV genome detract from the teaching of Richins et al is not persuasive. Richins et al disclosed the claimed FMV 34S promoter and taught that the FMV 34S promoter was expected to be a strong promoter like its counterpart the CaMV 35S promoter. The claimed FMV 34S promoter is the prior art FMV 34S promoter of Richins et al and the FMV 34S promoter is the only FMV promoter taught by Richins et al as being analogous in structure and function to the CaMV 35S promoter.

Appellant contends (Brief, page 11) that promoters deemed to be analogous to the CaMV 35S promoter are not reasonably expected to be strong promoters because Hasegawa et al (attached to Paper No. 12) found a strong promoter at another location in the genome of a soybean chlorotic mottle virus. This is not persuasive because viruses can have more than one strong promoter -- e.g., CaMV contains two strong promoters 19S and 35S. Furthermore, Hasegawa et al pointed out a promoter thought to be analogous to the CaMV 35S promoter (see Figure 7 which also shows the claimed FMV 34S promoter) but stated that the sequence of this promoter was <u>not</u> analogous structurally to that of CaMV 35S (page 10010). Because of the lack of sequence similarity, Hasegawa et al said

that transcription analysis was being done to prove that the putative mottle virus promoter actually corresponded to the CaMV 35S promoter. This was not the case with FMV as Richins et al clearly and unequivocally located and identified the FMV 34S promoter that corresponded to the CaMV 35S promoter long before this invention was made. Hasegawa et al does not dispute the location and identity of the FMV 34S promoter.

Discussions of possible polyA termination sites in the 3' untranscribed region of the gene (pages 8460-8461 Richins et al) could not possibly teach away from the invention as Appellant alleges (Brief, page 12). The invention is a promoter -- the untranscribed region at the other end of the structural gene. Promoter as used in this application refers to the untranscribed regulatory region 5' of the coding sequence. All promoters have TATA boxes. Furthermore, promoter as used here includes the TATA box and various subsets of sequences such as domains, subdomains or motifs having tissue-specific and developmentally responsive elements as well as silencer regions and enhancer regions and CAAT boxes and so forth i.e. anything contiguous with the coding sequence that lies 5' of the coding sequence is embraced by the term promoter in this specification. It would have been well within the ordinary level of skill in this art to clone such a 5' region with a reasonable expectation of encompassing the entire regulatory region guided by analogy to the size of the CaMV 35 region disclosed in the primary references.

There can be no hindsight when Richins et al disclosed the same promoter that Appellant now claims. Appellant may have been the first to name the promoter "34S" but this is not a trademark contest; the claimed FMV promoter by whatever name was already known long before the invention was made. The properties urged by Appellant (location and extent and strength, Brief, page 13) are the same properties disclosed by Richins et al. The FMV 34S promoter was expected to be strong and its location and extent were known as Richins et al taught that the promoter in Figure 5 was structurally and functionally analogous to the CaMV 35S promoter. Since the claimed FMV 34S promoter is the prior art FMV 34S promoter, properties possessed by the claimed FMV 34S promoter are also possessed by the prior art FMV 34S promoter.

Issue IV. Whether claims 20, 22-28, 30, 33-36 and 43 were properly rejected under 35 USC 103 as obvious over Shah et al and Sanders et al taken with Richens et al and Shepherd et al.

The rejection is based upon a combination of references and Shepherd et al need not provide teachings which are provided by Richins et al. Comments made above in relation to Richins et al are incorporated by reference; expectations of success do not have to be absolute only reasonable. The expectedly strong FMV 34S promoter was clearly identified by the cited prior art. Indeed, the claimed FMV 34S promoter is the prior art FMV 34S promoter and properties possessed by the claimed FMV 34S promoter are also possessed by the prior art FMV 34S promoter.

In addition to the DxS strain, Shepherd et al disclosed the

MS strain of FMV which was the source of the FMV 34S promoter of Figure 4 in this specification and the middle row of sequences in Figure 1 (sandwiched between the CaMV 35S promoter on top and the Richins et al FMV 34S promoter from strain DxS on the bottom). The specification as filed makes no distinction between the FMV 34S promoter of the MS strain and the FMV 34S promoter of the DxS strain even though there are some differences in the sequence. Appellant does not recognize a distinction between promoters of these two strains and has never urged separate patentability of the FMV 34S promoter of the MS strain. Claims 24-26 must stand or fall with claims 20, 22-23, 27-28, 30, 33-36 and 43.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

P. Moody
(703) 308-3724
February 21, 1995

P. Moody
PATRICIA R. MOODY
PRIMARY EXAMINER
GROUP 1800